K132413

510(k) Summary

SUBMITTER INFORMATION

A.	Company Name:	CareFusion
B.	Company Address:	10020 Pacific Mesa Blvd. San Diego, CA 92121
C.	Company Phone:	(858) 617-5925
	Company Fax:	(858) 617-5977
D.	Contact Person:	Michelle J. Badal
E.	Date Summary Prepared:	April 22, 2013

AUG 29 2013

DEVICE IDENTIFICATION

A. Trade Name: MZ1000

B. Common Name: IV Administration Set

C. Classification: IV Administration Set, Needleless Connector, Closed Access, (21 CFR 880.5440, Product Code FPA)

PREDICATE DEVICES

The MZ1000 is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
MaxPlus Tru-Swab Positive Displacement Connector	CareFusion (Formerly Medegen)	K072542	Sept 25, 2007
Neutron	ICU Medical Inc.	K100434	August 9, 2010
Neutral Luer Activated Device	Baxter Healthcare Corporation	K120443	May 22, 2012

DEVICE DESCRIPTION

The MZ1000 is a zero reflux needleless connector intended for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion, continuous infusion or aspiration of drugs, blood and fluids which using a vascular access device. The MZ1000 is a closed, luer activated device that eliminates the risk of needlestick injuries. The MZ1000 does not require a specific clamping sequence or technique in order to be used safely. The flush volume for the MZ1000 is five milliliters (5ml). The MZ1000 can be used for seven (7) days and 200 activations.

INTENDED USE

The MZ1000 is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. The MZ1000 can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics
Zero reflux
Low flush volume - 5ml
7 days & 200 activations
Needleless Connector
No interstitial or dead space internal to the connector
Non-hemolytic
Flow rate of >6L/hour
325 psi & maximum flow rate of 10ml/seconds
Disinfect with 70% IPA
Device can be cleansed with 2% chlorhexidine gluconate or iodine

PERFORMANCE DATA

The MZ1000 (subject device) met all of the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility and other performance criteria which verify it to be substantially equivalent to the predicate devices. Results of the testing demonstrate that there are no new issues of safety and efficacy that are raised with the MZ1000.

SUBSTANTIAL EQUIVALENCE

The results of the testing demonstrate that there are no new issues of safety and efficacy that are raised with the introduction of the MZ1000. The results also demonstrate substantial equivalence to the predicate devices, and that they are safe and effective for their intended use.

CLINICAL AND NON-CLINICAL DATA:

There is no clinical data included in this submission. Non-clinical data (bench testing) is included in the MZ1000 Performance Testing section in the submission as simulated use environmental testing. The testing included functional, microbial ingress, sterility, and other performance criteria to verify the safe and effective use of the device. The results of the testing demonstrates that there are no differences between the predicate and the subject device that raise any new issues of safety or effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

CareFusion
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K132413
Trade/Device Name: Intravascular Administration Set, Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 31, 2013
Received: August 14, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Carefusion

Indications for Use

510(k) Number (if known): K132413

Device Name: MZ1000

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The MZ1000 is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. The MZ1000 can be used for direct injection, intermittent infusion, continuous infusion or aspiration

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

FDA

Richard C. Chapman
2013.08.28
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